Sample Clinical Quality Management Plan Annual Summary Report

(SAMPLE ONLY. The Division of AIDS (DAIDS) requires site personnel to evaluate both their Clinical Quality Management Plans (CQMP) and overall Quality Management (QA and QC) activities annually. Documentation of these evaluations may be satisfied with the submission of the Non-competing Grant Progress Report (type 5 annual reports). While completing this report will satisfy the documentation requirements for these evaluations, submitting the information below in any format is acceptable.)

Site Name:_____ **Site Number**_____

Person Preparing Report_____ **Date of Report**_____

The Division of AIDS (DAIDS) requires site personnel to evaluate Clinical Quality Management Plans (CQMPs) annually. Please summarize Quality Management (QM) activities over the past year. Please complete this form and submit it utilizing the DAIDS specified format e.g., Type 5 grant progress report.

1. What opportunities for improvement have been identified during the past year as a result of ongoing Quality Assurance (QA) and Quality Control (QC) activities? Describe.

2. Which key indicators reviewed during your QM processes revealed a need for improvement?

Informed consent form and process	____	Clinical endpoint identification	____
Eligibility criteria	____	Identification and reporting of Serious	
Scheduled tests and procedures	____	Adverse Events (SAE), DAIDS	
Missed visits, tests or procedures	____	Expedited Adverse Events (EAE) and	
Concomitant/prohibited medications	____	Adverse Events (AE)	____
Study product administration/dosing	____		

3. For QA/QC problem trends or ineffective processes and tools that were identified, what corrective action plans were put into place? Describe.

4. What QA/QC tools are included in your CQMP? List all.

5. Were all QA/QC activities defined within the CQMP performed? Were all stated frequencies of review met? Describe.

6. Does the CQMP require any modifications? Describe.